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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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THE MAXHAM FIRM				
9330 SCRANTON ROAD, SUITE 350				
SAN DIEGO, CA 92121				
EXAMINER				
WOODALL, NICHOLAS W				
ART UNIT		PAPER NUMBER		
3775				
MAIL DATE		DELIVERY MODE		
08/06/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/540,089

Applicant(s)

BRANEMARK, PER-INGVAR

Examiner

Nicholas Woodall

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-14, 16-20, 22-34, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14, 16-20, 22-34, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to applicant's amendment received on 04/20/2009.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 37 includes the new limitation requiring the device to have a ratio between the length of the anchoring portion and the largest external diameter of the screw thread that is greater than 3. The applicant then stated that the specification provides a single embodiment shown in the Figures of the application that meet this requirement and is therefore supported by the specification. The examiner disagrees with the applicant regarding the new limitation being supported by the originally filed specification. MPEP 2163 states that in order to comply with the written description requirement of 35 U.S.C. 112 first paragraph each claim must be explicitly, implicitly, or inherently supported in the original filed disclosure. First, the limitation is not explicitly stated since the specification does not state that the length of the anchoring portion must be at least three times larger than the largest diameter of the screw thread. Furthermore, the specification does not state that if a specific length of an

anchoring portion is used, for example 18 mm, that a specific thread diameter must be used, i.e. no larger than 6 mm, to provide a three to one ratio between length of the anchoring portion and the largest thread diameter. Second, the limitation is not implicitly stated since the application states that a variety of anchoring lengths between 10 mm and 20 mm may be used as well as any sized thread, but an M6 thread is shown for in the Figures (page 5 lines 20-25). MPEP 2163 states that when the limitation of a claim is not explicitly provided in the written description it must be shown that a person having ordinary skill in the art would have understood, at the time the application was filed, that the description requires this limitation. Since the specification states that any length between about 10 mm to about 20 mm may be used with any known thread size, it would not be understood by one having ordinary skill in the art to use a length and a thread size to have a ratio greater than three. Furthermore, even if one having ordinary skill in the art would only think to use an M6 thread size, the variable anchor portion length would provide some combinations, for example a length of 10 mm with the M6 thread, that is less than the ratio required by the limitation and it would not be understood by one having ordinary skill in the art to use only the lengths and with the M6 thread size to have a ratio greater than three. Third, the limitation is not inherently stated in the application. MPEP 2163 states that to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of

circumstances is not sufficient. The mere fact that the specification provide a range of anchor portion lengths, i.e. 10mm to 20 mm, and one potential thread size, i.e. M6 thread size, wherein some of the combination produce the ratio of the anchor portion length being three times larger than the largest thread diameter does not show inherency and therefore the claim limitation is not inherently described within the specification. Based on the reasons discussed above the examiner believes that the new limitation in claim 37 directed to the ratio between the anchor portion length and the largest diameter of the thread is not supported by the disclosure as originally filed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 11-14, 16-20, 22-34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Branemark (U.S. Patent 5,171,284) in view of Lemos (U.S. Patent 3,979,829).

Branemark discloses a titanium device comprising a generally cylindrical anchoring portion formed with an insertion end and having an external screw thread (6), a cavity having a circular cross-section that widens towards the insertion end and opens out at the insertion end, and a plurality of through-penetrating slots (8 and 9) extending from the insertion end that connect the cavity to the outside of the anchoring portion, wherein the slots direct material, such as shavings, from outside the device into the

cavity (see Figure 5 of the reference). The slots including a leading slot wall surface and a trailing slot wall surface related to the direction of rotation, wherein each surface faces into the slot and the outermost portion of the trailing wall surface defines a cutting edge at an angle, i.e. approximately 90 degrees as shown in Figure 5 of the reference, relative to the outside of the anchoring portion. Branemark fails to disclose the device wherein the trailing slot wall surface is at an acute angle relative to the outside of the anchoring portion with the radial direction and the trailing slot wall surface sloping obliquely forward from within and outwardly in the direction of rotation and wherein the leading slot wall surface is parallel to the trailing slot wall surface. Lemos teaches a device comprising through-penetrating slots (34) connected to a cavity (24) including a trailing slot wall surface (37) defining an edge at an acute angle relative to the outside of the device with the radial direction and the trailing slot wall surface sloping obliquely forward from within and outwardly in the direction of rotation (36) and wherein the leading slot wall surface (33) is parallel to the trailing slot wall surface in order to increase the migration of material outside of the device into the cavity (column 6 lines 7-20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Branemark wherein the trailing slot wall surface and the leading slot wall surface of the slots are provided at an angle in view of Lemos in order to increase the migration of material outside the device onto the cavity.

The device of Branemark as modified by Lemos discloses the invention as claimed except for the angle at the radially outer end of the trailing slot wall surface is 20-40 degrees, the angle at the radially outer end of the trailing slot wall surface is 27-

33 degrees, the plurality of slots includes 5-7 slots, and the slot width at the radially outer end of the slot corresponds to 15-35 percent of the peripheral distance between two slots on the outside of the device. Regarding the angle being 20-40 degrees or 27-33 degrees, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Branemark as modified by Lemos wherein the angle is 20-40 degrees or 27-33 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding the plurality of slots includes 5-7 slots, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Branemark as modified by Lemos wherein the plurality of slots includes 5-7 slots, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding the slot width at the radially outer end of the slot corresponds to 15-35 percent of the peripheral distance between two slots on the outside of the device, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Branemark as modified by Lemos wherein the slot width at the radially outer end of the slot corresponds to 15-35 percent of the peripheral distance between two slots on the outside of the device., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

6. Applicant's arguments filed 04/20/2009 have been fully considered but they are not persuasive. The applicant's argument that the device of Branemark as modified Lemos does not disclose the invention as claimed is not persuasive. The applicant argues that Branemark does not disclose the specific structure of a cutting edge as described in claim 1 and that the teachings of Lemos does not teach the limitations missing from the Branemark reference. The examiner disagrees with the applicant's argument. First, Branemark discloses a device comprising slots having a leading wall and a trailing wall that defines a cutting edge as discussed above, wherein the slot cuts bone and directs material, such as shavings, from the outside of the device into the cavity. The leading and trailing walls of the slots are at an angle that appears to be less than 90 degrees relative to the outside portion of the device but the angle is not explicitly stated in the reference (see Figure 5 of the reference). The cutting edge is the edge formed by the intersection of the trailing wall of the slot and the outside surface of the device and is therefore provided at the same angle to the outside of the device as the trailing wall, so if the training wall is provided at an acute angle than the edge is provided at an acute angle. Therefore, the Branemark discloses the invention as claimed except the trailing slot wall surface being at an acute angle relative to the outside of the anchoring portion with the radial direction and the trailing slot wall surface sloping obliquely forward from within and outwardly in the direction of rotation and wherein the leading slot wall surface is parallel to the trailing slot wall surface. Lemos teaches a device comprising slots that extend from the outside of the device to a cavity

as discussed above wherein the trailing slot wall surface defines an edge at an acute angle relative to the outside of the device with the radial direction and the trailing slot wall surface sloping obliquely forward from within and outwardly in the direction of rotation and wherein the leading slot wall surface (33) is parallel to the trailing slot wall surface in order to increase the migration of material directed from the outside of the device into the cavity. Therefore, the modification of the Branemark device by the teachings of the Lemos reference would make the slots of the Branemark device perform the function of directing material from outside the device into the cavity better. The applicant's argument that Lemos does not disclose slots with cutting edges is moot. Branemark already discloses the slot having a cutting edge that is defined by the trailing wall as discussed above. The examiner is using the Lemos reference to teach providing the trailing wall and the leading wall at a position relative to the outside of the device in order to increase the migration of material directed from the outside of the device into the cavity. The device of Branemark as modified by Lemos would include slots wherein the trailing wall is at an acute angle relative to the outside of the device, which would also provide the cutting edge at an acute angle relative to the outside of the device since the edge is formed by the intersection of the trailing wall and the outside of the device as discussed above. Therefore, the examiner believes that the rejection under 103(a) is proper and that the rejection meets all the limitations of the claims as presented. The examiner has not provided a new ground of rejection not necessitated by the amendment, but the examiner improperly called the slots of the Lemos reference cutting slots, which the examiner has fixed in the rejection above. Since this change

may be constituted as changing the scope of the rejection and providing a new ground of rejection the examiner is making this office action non-final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775